MEDICATED BODY- menthol and zinc oxide powder
Universal Distribution Center LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Medicated Body Powder

Active Ingredients

Menthol 0.15%

Zinc Oxide 1.0%

Purpose

External analgesic

Skin protectant

Uses

for the temporary relief of pain and itching associated with:

- Backache
- Minor Burns
- Minor Skin Irritations
- Minor Cuts
- Sunburn
- Insect Bites
- Ooozing and weeping of poison ivy, poison oak and poison sumac can be dried using Universal Medicated Powder

Warnings

For external use only.

When using this product avoid contact with the eyes.

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Directions

- Adults and children 2 years of age and older: apply to affected area no more than 3 to 4 times daily
- Children under 2 years of age: consult a doctor
- For best results, dry area thoroughly before applying

Inactive Ingredients

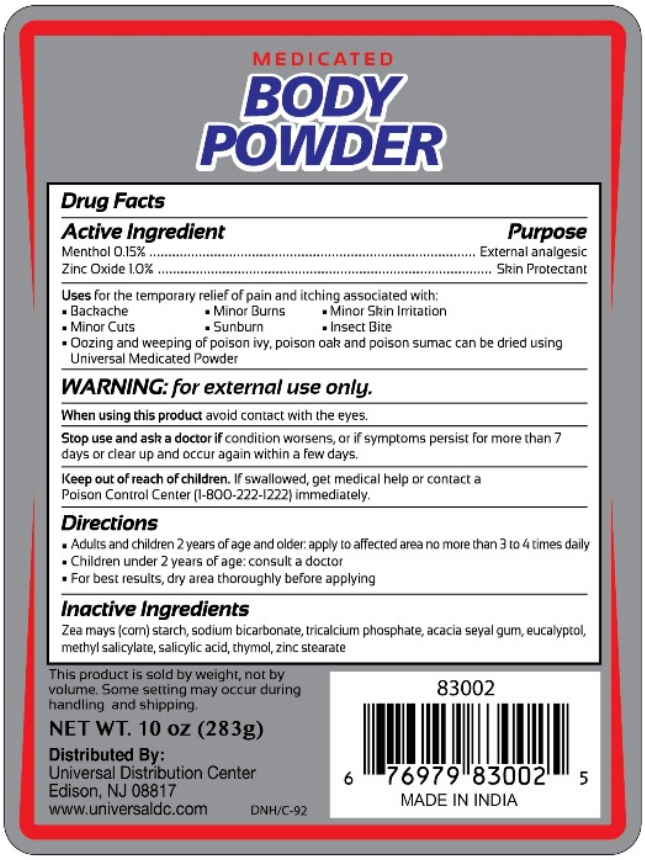
Zea mays (corn) starch, sodium bicarbonate, tricalcium phosphate, acacia seyal gum, eucalyptol, methyl salicylate, salicylic acid, thymol, zinc stearate

This product is sold by weight, not by volume. Some settling may occur during handling and shipping.

Principal Display Panel

Medicated Body Powder

NET WT. 10 oz (283 g)



MEDICATED BODY

menthol and zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52000-038
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.5 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	10 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

GUM TALHA (UNII: H18F76G097)	
EUCALYPTOL (UNII: RV6J6604TK)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
THYMOL (UNII: 3J50XA376E)	
ZINC STEARATE (UNII: H92E6QA4FV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-038-25	283 g in 1 BOTTLE; Type 0: Not a Combination Product	12/04/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/04/2017	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(52000-038)

Revised: 12/2017 Universal Distribution Center LLC